SEP - 7 2001

K012836

GE Medical Systems
P.O. Box 414, NB-918
Milwaukee, WI 53201

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h)

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Senior Regulatory Programs Manager
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Date Prepared: August 22, 2001

Device Name: LightSpeed Plus Mobile Computed Tomography System.
Computed Tomography X-ray System, 21 CFR 892.1750, 90-JAK

Marketed Device: GE Medical System's LightSpeed Plus Computed Tomography System; 510(k) Number K000300, currently in commercial distribution.

Device Description:

The GE LightSpeed Plus Mobile CT Scanner System is composed of a gantry, patient table, image acquisition hardware and software, an operator console, and associated accessories. Materials and construction are equivalent to the LightSpeed Plus CT Scanner System and are compliant with UL2601-1, IEC 60601-1 and associated collateral standards, and applicable sections of 21 CFR Subchapter J.

Indications for Use:

The LightSpeed Plus CT Scanner System is indicated for head and whole body X-ray computed tomography applications. It can be operated in a mobile as well as a fixed site environment.

Comparison with Predicate Device:

The GE LightSpeed Plus Mobile Computed Tomography System is a modification of, and of comparable type and substantially equivalent to the currently marketed GE LightSpeed Plus CT System. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended use as the predicate device.

Summary of Studies:

The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety and performance standards.

Conclusion:

Intended use and fundamental scientific technology are the same as the legally marketed GE LightSpeed Plus CT System. The design and development process of the manufacturer conforms with 21 CFR 820, and ISO 9001/ EN 46001 quality systems. The device conforms to applicable medical device safety and performance standards. Results of the testing and standards conformance described above demonstrate, in the opinion of GE Medical Systems, that the LightSpeed Plus Mobile CT System is substantially equivalent to the currently cleared LightSpeed Plus CT System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, NB-918
MILWAUKEE WI 53201

Re: K012836
LightSpeed Plus Mobil CT System
(Computed Tomography X-Ray System)
Dated: August 22, 2001
Received: August 23, 2001
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K012836

Device Name: **LightSpeed Plus Mobile CT System**

Indications for Use

The LightSpeed Plus CT Scanner System is indicated for head and whole body X-ray computed tomography applications. It can be operated in a mobile as well as a fixed site environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012836